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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,223	12/27/2000	Robert H. Daniels	5100-0005	6599

20855 7590 10/28/2002

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EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/750,223	DANIELS ET AL.	
	Examin r	Art Unit	
	Gary W. Counts	1641	

-- Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-102* is/are pending in the application.

4a) Of the above claim(s) *22-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 and 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-21 in Paper No. 7 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim recites determining the amount of an analyte of interest in a test sample but the claim does not recite method steps for determining the amount of an analyte of interest in a test sample.

Claim 1, line 5 "and/or" is vague and indefinite. The phrase "and/or" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claim 1, line 13 the recitation "capable of" is vague and indefinite. Does the first detection ligand selectively bind a first target moiety of the analyte or not?

Claim 1, line17 the recitation "capable of" is vague and indefinite. Does the semiconductor nanocrystal emit light of a characteristic emission peak or not?

Claim 1, line 22 the recitation "capable of" is vague and indefinite. Does the capture ligand selectively bind the first detection complex or not?

Claim 1, line 26 the recitation "capable of" is vague and indefinite. Does the control ligand selectively bind the first detection ligand or not?

Claim 1, part (D) (iii) the recitation "via" is vague and indefinite. It is unclear what the term encompasses.

Claim 1, part (D) (II) "the production of light" there is insufficient antecedent basis for this limitation.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5, 10, 11, 13-15, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al (US 6,352,862) in view of Bruchez et al (US 6,274,323).

Davis et al disclose quantitative and qualitative methods for determining an analyte of interest. Davis et al disclose applying the sample to a test strip which comprises an aperture (Figure 4, (401))(sample reservoir). Davis et al disclose a chromatographic strip such as a strip of nitrocellulose. Davis et al disclose a labeled specific binding reagent in the dry state which binds the analyte (col 2, lines 4-15). Davis et al disclose that this label can be any entity the presence of which can be

readily detected (col 6, lines 42-53). Davis et al disclose an unlabelled specific binding reagent, which is permanently immobilized (capture reagent) in a detection zone on the strip. Davis et al disclose that the labeled and unlabelled reagents participate in a sandwich reaction in the presence of the analyte (col 1, lines 53-67). Davis et al also disclose a control zone which comprises an immobilized antibody that will bind to the labeled reagent. Davis et al disclose that the control zone is located downstream of the detection zone (col 6, lines 23-41). Davis et al disclose that the test strip has a first end and a second end and the sample reservoir is located at the first end and the sample mixture flows from the first end to the second end. Davis et al also disclose exposing the test strip to a light source to determine the presence of the analyte in the test sample (col 6, line 42- col 7, line 29).

Davis et al differ from the instant invention in failing to disclose the first detection ligand is conjugated with a semiconductor nanocrystal.

Bruchez et al disclose semiconductor nanocrystals as detection reagents in immunoassays. Bruchez et al disclose that when semiconductor nanocrystals are irradiated with an energy source, such as an excitation light source. The semiconductor nanocrystal emits a characteristic emission spectrum, which can be observed and measured (col 4, lines 43-61). Bruchez et al disclose that these semiconductor nanocrystals can be couple to antibodies (col 23). Bruchez et al also disclose that the specific-binding molecule may comprise a nucleic acid molecule (col 8, lines 1-10). Bruchez et al disclose that these coupled semiconductor nanocrystals can be used in solid phase assays (col 25 lines 43-67). Bruchez et al disclose that these

semiconductor nanocrystal labels provide (i) high fluorescent intensity, (ii) adequate separation between the absorption and emission frequencies, (iii) good solubility, (iv) ability to be readily linked to other molecules, (v) stability towards harsh conditions and high temperatures, (vi) a symmetric, nearly gaussian emission lineshape for easy deconvolution of multiple colors, and (vii) compatibility with automated analysis. And at present time, none of the convention fluorescent labels satisfy all of the requirements.

It would have been obvious to one of ordinary skill to incorporate semiconductor nanocrystals as taught by Bruchez et al into the method of Davis et al because Bruchez et al shows that these semiconductor nanocrystal labels provide (i) high fluorescent intensity, (ii) adequate separation between the absorption and emission frequencies, (iii) good solubility, (iv) ability to be readily linked to other molecules, (v) stability towards harsh conditions and high temperatures, (vi) a symmetric, nearly gaussian emission lineshape for easy deconvolution of multiple colors, and (vii) compatibility with automated analysis. And at present time, none of the convention fluorescent labels satisfy all of the requirements.

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al and Bruchez et al in view of Bawendi et al (US 6,444,143).

See above for teachings of Davis et al and Bruchez et al.

Davis et al and Bruchez et al differ from the instant invention in failing to teach a microsphere conjugated directly to the detection ligand, wherein the microsphere is dyed with the semiconductor nanocrystals.

Bawendi et al disclose quantum dots (semiconductor nanaocrystals) coupled to beads (microspheres) (col 11, lines 30-40. Bawendi et al disclose that these quantum dots coupled to beads provides the advantage of tracking or identifying an article of interest.

It would have been obvious to one of ordinary skill in the art to incorporate quantum dots coupled to beads as taught by Bawendi et al into the modified method of Davis et al and Bruchez et al because Bawendi et al teaches that these quantum dots coupled to beads provides the advantage of tracking or identifying an article of interest.

7. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al and Bruchez et al in view of Bawendi et al as applied to claims 1-7, 10, 11, 13-15 and 17-19 above and further in view of Weiss et al (US 5,990,479).

See above for teachings of Davis et al, Bruchez et al and Bawendi et al.

Davis et al, Bruchez et al and Bawendi et al differ from the instant invention in failing to teach the nanocrystals are contained within the interior of the microsphere.

Weiss et al disclose glass coated semiconductor nanocrystals (microsphere). Weiss et al disclose that the nanocrystal is within the glass particle (col 7, lines 6-63). Weiss et al disclose that the use of such microspheres provide for the detection of one or more detectable substances in organic materials, and in particular to the detection of one or more detectable substances in biological materials.

It would have been obvious to one of ordinary skill in the art to incorporate microspheres as taught by Weiss et al into the modified method of Davis et al and Bruchez et al because Weiss et al shows that the use of such microspheres provide for

the detection of one or more detectable substances in organic materials, and in particular to the detection of one or more detectable substances in biological materials.

8. Claims 12, 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al and Bruchez et al in view of Bawendi et al (US 6306,610).

See above for teachings of Davis et al and Bruchez et al.

Davis et al and Bruchez et al differ from the instant invention in failing to teach the protein is an enzyme.

Bawendi et al disclose binding pairs used in quantum dot assays. Bawendi et al disclose exemplary binding pairs such as enzyme-enzyme cofactor and enzyme-enzyme-inhibitor (col 6, line 51 – col 7, line 7). The use of such exemplary binding pairs provide first and second molecules that specifically bind to each other with greater affinity and specificity than to other components in the sample.

It would have been obvious to one of ordinary skill in the art to incorporate the use of enzymes as taught by Bawendi et al into the modified method of Davis and Bruchez et al in order to provide first and second molecules that specifically bind to each other with greater affinity and specificity than to other components in the sample.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al and Bruchez et al in view of Lee et al.

See above for teachings of Davis et al and Bruchez et al.

Davis et al and Bruchez et al differ from the instant invention in failing to teach the control ligand is a nucleic acid molecule.

Lee et al disclose the ligand or control reagent may be a protein, peptide, amino acid, nucleic acid or hormone (col 6, line 59 – col 7 line7).

It would have been obvious to one of ordinary skill in the art to incorporate a nucleic acid as taught by Lee et al into the modified method of Davis et al and Bruchez et al because it would provide a molecule to which a molecule of interest will bind.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
October 17, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
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10/21/02